

DETAILED ACTION

Election/Restrictions

Newly submitted claims 72-77 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims recite a patentably distinct method/mode of operation for producing a kink-resistant walled tube

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 72-77 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

Applicant's amendment to the claims filed March 22, 2010 has been entered. Claims 1-50 and 66 have been canceled. Claims 72-77 have been withdrawn from consideration. Claims 51 and 62 are currently amended. Claims 67-71 are new. Claims 51-65 and 67-71

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 67 recites that it depends from claim 66. Claim 66 has been canceled. It is unclear from which claim the claim is intended to depend. Claim 68 recites "modifying the parts of the multiple-part mandrel". There is insufficient antecedent basis for this limitation in the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51-65 and 67-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,534,317 in view of either of Brown et al. (US 5,558,737) or Stevens (US 3,585,707). Although the conflicting claims are not identical, they are not patentably distinct from each. Claim 1 of the ‘317 patent claims a process for manufacturing a kink resistant sheath comprising coating a mandrel with a first layer of plastic material to form an inner tube; placing a braid over the inner tube; placing a spring reinforcement over the braid; and coating the braid with a second layer to form an outer tube of braid-reinforced sheath.

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Regarding claim 51, claim 1 of the '317 patent effectively claims all of the elements set forth in claim 51 except modifying the mandrels size after the spring-reinforced tube is formed. However, each of Brown et al. (Figure 6; Figure 7; col. 7, line 40-col. 8, line 44; particularly – col. 8, lines 22 [applicable to a spring] and 35-44 [remove by disintegration]) and Stevens (Abstract; col. 2, lines 15-20; col. 3, lines 5-47) suggest analogous methods wherein after forming the tube/catheter with a mandrel/core the mandrel/core is removed by modifying the mandrel's size (Brown et al.: disintegration; Stevens: stretching to reduce the core's diameter/width). Therefore it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the claimed method of the '317 patent and to have modified the size of the mandrel, as suggested by either of Brown et al. or Stevens, for the purpose of removing the mandrel in an art recognized suitable and effective manner.

As to claims 52-65 and 67-71, claim 1 of the '317 claims the layers of tubing are applied by "coating". In the context of the '317 patent, the term "coating" is understood to include dipping/molding and extrusion processes. As such, one having ordinary skill would have understood the term coating, within the context of the '317 patent, to include dipping/molding and extrusion processes. As such, claim 1 of the '317 effectively renders claims 52-65 anticipated and/or obvious in view of a proper construction of the terms in the '317 patent. Additionally, claims 67-71 recite conventional mandrel variants.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51, 53-57, 59-61 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al. (US 5,888,436).

Regarding claims 51, 53-57, 59-61, and 68, Keith et al. teach a method of producing a variable stiffness microtubing comprising coating a mandrel (29 or 30) with a first layer of plastic/resin material (13); placing a coiled wire (i.e. spring) reinforcement over the first layer (col. 3, lines 65-col. 4, line 1); and coating the coiled wire/spring reinforced layer with a second layer of resin/plastic (22) to form a reinforced microtube (Figure 1A). The second layer of resin/plastic may be applied in a variety of manners, including extrusion (col. 4, lines 47-64). Further, the mandrel is tapered and each tapered part is understood to provide a separate part in a multiple-part mandrel (Figure 1C). The coiled wire is made of metal. Further, upon completion of microtubing, Keith teaches cutting the mandrel (29 or 30) (i.e. modifying the mandrel's size) or cutting the wider short segment "b" from the mandrel (i.e. modifying the mandrel size and also reducing the overall diameter/width of the mandrel) (col. 5, lines 8-25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-55, 57, 59-61 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US 5,792,116) in view of either of Brown et al. (US 5,558,737) or Stevens (US 3,585,707).

Regarding claims 51-55, 57, 59-61 and 68, Berg et al. teach forming a catheter having a geometrically shaped inner surface (Abstract) wherein a mandrel/core having an outer surface geometrically configured is employed (col. 4, lines 38-52). In the method, the mandrel is coated with a first extruded inner tubular layer, a plurality of strands are wrapped over the first layer, and a second outer tubular is extruded over the strands (col. 4, lines 38-52). Berg et al. teach the plurality of strands are applied in the form of a braid or are helically wrapped (i.e. in a coiled spring configuration) onto the inner layer to form a middle layer (col. 8, lines 15-24). Berg et al. do not teach modifying the mandrel's size after the spring-reinforced tube is formed.

However, each of Brown et al. (Figure 6; Figure 7; col. 7, line 40-col. 8, line 44; particularly – col. 8, lines 22 [applicable to a spring] and 35-44 [remove by disintegration]) and Stevens (Abstract; col. 2, lines 15-20; col. 3, lines 5-47) suggest analogous methods wherein after forming the tube/catheter with a mandrel/core the mandrel/core is removed by modifying

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the mandrel's size (Brown et al.: disintegration; Stevens: stretching to reduce the core's diameter/width).

Therefore it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the claimed method of Berg et al. and to have modified the size of the mandrel, as suggested by either of Brown et al. or Stevens, for the purpose of removing the mandrel in an art recognized suitable and effective manner.

Claims 51-53, 55-58, 60, and 68 are rejected under 35 U.S.C. 103(a) as being obvious over Taylor (US 6,464,632) in view of either of Brown et al. (US 5,558,737) or Stevens (US 3,585,707).

Regarding claims 51-53, 55-58, 60 and 68, Taylor teaches a method of producing a flexible liner comprising coating a mandrel (704) with an extruded plastic tubular material; placing a spring reinforcement over the first layer; and coating the spring reinforcement with multiple layers by dipping the material in a polymer dissolved in a solvent (Figures 7A-7E; col. 8, lines 47-col. 9, line 40). Taylor et al. do not teach modifying the mandrel's size after the spring-reinforced tube is formed.

However, each of Brown et al. (Figure 6; Figure 7; col. 7, line 40-col. 8, line 44; particularly – col. 8, lines 22 [applicable to a spring] and 35-44 [remove by disintegration]) and Stevens (Abstract; col. 2, lines 15-20; col. 3, lines 5-47) suggest analogous methods wherein after forming the tube/catheter with a mandrel/core the mandrel/core is removed by modifying the mandrel's size (Brown et al.: disintegration; Stevens: stretching to reduce the core's diameter/width).

Therefore it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the claimed method of Taylor et al. and to have modified

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the size of the mandrel, as suggested by either of Brown et al. or Stevens, for the purpose of removing the mandrel in an art recognized suitable and effective manner.

Claims 51, 53, 55-58, and 68 are rejected under 35 U.S.C. 103(a) as being obvious Sutton (US 5,472,435) in view of either of Brown et al. (US 5,558,737) or Stevens (US 3,585,707).

Regarding claims 51, 53, 55-58, and 68, Sutton teaches a method of producing a drainage catheter comprising coating a mandrel (72) with a polymeric material to form a first layer; applying a spring reinforcement (Figure 11) over the first layer; and dipping the spring reinforced layer in a solvent based solution to form a second layer of the tube (Figure 15; Table D; col. 10, lines 4-col. 11, line 14). Sutton does not teach modifying the mandrel's size after the spring-reinforced tube is formed.

However, each of Brown et al. (Figure 6; Figure 7; col. 7, line 40-col. 8, line 44; particularly – col. 8, lines 22 [applicable to a spring] and 35-44 [remove by disintegration]) and Stevens (Abstract; col. 2, lines 15-20; col. 3, lines 5-47) suggest analogous methods wherein after forming the tube/catheter with a mandrel/core the mandrel/core is removed by modifying the mandrel's size (Brown et al.: disintegration; Stevens: stretching to reduce the core's diameter/width).

Therefore it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the claimed method of Sutton and to have modified the size of the mandrel, as suggested by either of Brown et al. or Stevens, for the purpose of removing the mandrel in an art recognized suitable and effective manner.

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Claims 59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (US 6,464,632) in view of either of Brown et al. (US 5,558,737) or Stevens (US 3,585,707), as applied to claims 51-53, 55-58, and 68 above, and further in view of any of Keith et al. (US 5,888,436) or Chiu et al. (US 6,540,734) or Kolobow (US 5,429,127) or Crowley (US 5,840,031).

As to claims 59 and 61, the combination teaches the method set forth above but Taylor does not teach the mandrel is tapered/has multiple parts. However, each of Keith (Figure 1C), Chiu (Figure 21D), Kolobow (col. 12, lines 32-36), and Crowley (col. 10, lines 60-67) teach that in the art of producing catheters it is known to employ tapered mandrels/mandrels having a variety of sections (i.e. multiple parts).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Taylor and to have employed a mandrel having a tapered part/having a plurality of parts (e.g. a cylindrical part and a tapered part) for the purpose, as suggested by the secondary references, of producing a catheter having a suitable shape for insertion and use.

Claims 59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton (US 5,472,435) in view of either of Brown et al. (US 5,558,737) or Stevens (US 3,585,707), as applied to claims 51, 53, 55-58, and 68 above, and further in view of any of Keith et al. (US 5,888,436) or Chiu et al. (US 6,540,734) or Kolobow (US 5,429,127) or Crowley (US 5,840,031).

As to claims 59 and 61, the combination teaches the method set forth above but Sutton does not teach the mandrel is tapered/has multiple parts. However, each of Keith (Figure 1C), Chiu (Figure 21D), Kolobow (col. 12, lines 32-36), and Crowley (col. 10, lines 60-67) teach that

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in the art of producing catheters it is known to employ tapered mandrels/mandrels having a variety of sections (i.e. multiple parts).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Sutton and to have employed a mandrel having a tapered part/having a plurality of parts (e.g. a cylindrical part and a tapered part) for the purpose, as suggested by the secondary references, of producing a catheter having a suitable shape for insertion and use.

Claims 62-65, 67, and 69 are rejected under 35 U.S.C. 103(a) as being obvious over Taylor (US 6,464,632) in view of any one of Keith et al. (US 5,888,436) or Chiu et al. (US 6,540,734) or Kolobow (US 5,429,127) or Crowley (US 5,840,031) and in view of either Brown et al. (US 5,558,737) or Stevens (US 3,585,707).

Regarding claims 62-65, 67 and 69, Taylor teaches a method of producing a flexible liner comprising coating a mandrel (704) with an extruded plastic tubular material; placing a spring reinforcement over the first layer; and coating the spring reinforcement with multiple layers by dipping the material in a polymer dissolved in a solvent (Figures 7A-7E; col. 8, lines 47-col. 9, line 40). Taylor does not teach the mandrel is tapered/stepped/has multiple sections/multiple parts. However, each of Keith (Figure 1C), Chiu (Figure 21D), Kolobow (col. 12, lines 32-36), and Crowley (col. 10, lines 60-67) teach that in the art of producing catheters it is known to employ tapered mandrels/mandrels having a variety of sections (i.e. multiple parts).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Taylor and to have employed a mandrel having a tapered part/having a plurality of parts (e.g. a cylindrical part and a tapered

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part) for the purpose, as suggested by the secondary references, of producing a catheter having a suitable shape for insertion and use.

Further, Taylor et al. do not teach modifying the mandrel's size after the spring-reinforced tube is formed. However, each of Brown et al. (Figure 6; Figure 7; col. 7, line 40-col. 8, line 44; particularly – col. 8, lines 22 [applicable to a spring] and 35-44 [remove by disintegration/collapse]) and Stevens (Abstract; col. 2, lines 15-20; col. 3, lines 5-47) suggest analogous methods wherein after forming the tube/catheter with a mandrel/core the mandrel/core is removed by modifying the mandrel's size (Brown et al.: disintegration; Stevens: stretching to reduce the core's diameter/width).

Therefore it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the claimed method of Taylor et al. and to have modified the size of the mandrel, as suggested by either of Brown et al. or Stevens, for the purpose of removing the mandrel in an art recognized suitable and effective manner.

Claims 62-65, 67, and 69 are rejected under 35 U.S.C. 103(a) as being obvious over Sutton (US 5,472,435) in view of any one of Keith et al. (US 5,888,436) or Chiu et al. (US 6,540,734) or Kolobow (US 5,429,127) or Crowley (US 5,840,031) and in view of either Brown et al. (US 5,558,737) or Stevens (US 3,585,707).

Regarding claims 62-65, 67 and 69, Sutton teaches a method of producing a drainage catheter comprising coating a mandrel (72) with a polymeric material to form a first layer; applying a spring reinforcement (Figure 11) over the first layer; and dipping the spring reinforced layer in a solvent based solution to form a second layer of the tube (Figure 15; Table D; col. 10, lines 4-col. 11, line 14).

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Sutton does not teach the mandrel is tapered/stepped/has multiple sections/multiple parts. However, each of Keith (Figure 1C), Chiu (Figure 21D), Kolobow (col. 12, lines 32-36), and Crowley (col. 10, lines 60-67) teach that in the art of producing catheters it is known to employ tapered mandrels/mandrels having a variety of sections (i.e. multiple parts).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Sutton and to have employed a mandrel having a tapered part/having a plurality of parts (e.g. a cylindrical part and a tapered part) for the purpose, as suggested by the secondary references, of producing a catheter having a suitable shape for insertion and use.

Further, Sutton does not teach modifying the mandrel's size after the spring-reinforced tube is formed. However, each of Brown et al. (Figure 6; Figure 7; col. 7, line 40-col. 8, line 44; particularly – col. 8, lines 22 [applicable to a spring] and 35-44 [remove by disintegration/collapse]) and Stevens (Abstract; col. 2, lines 15-20; col. 3, lines 5-47) suggest analogous methods wherein after forming the tube/catheter with a mandrel/core the mandrel/core is removed by modifying the mandrel's size (Brown et al.: disintegration; Stevens: stretching to reduce the core's diameter/width).

Therefore it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the claimed method of Sutton and to have modified the size of the mandrel, as suggested by either of Brown et al. or Stevens, for the purpose of removing the mandrel in an art recognized suitable and effective manner.

Claims 70 and 71 are rejected under 35 U.S.C. 103(a) as being obvious over Taylor (US 6,464,632) in view of any one of Keith et al. (US 5,888,436) or Chiu et al. (US 6,540,734) or Kolobow (US 5,429,127) or Crowley (US 5,840,031) and in view of either Brown et al. (US

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5,558,737) or Stevens (US 3,585,707), as applied to claims 62-65, 67, and 69 above, and further in view of Honningstad et al. (US 3,113,897).

As to claims 70 and 71, the combination teaches the method set forth above. Taylor does not teach applying electrical energy to the mandrel. However, Honningstad et al. teach a method of making a reinforced plastic tube wherein the mandrel is removed by inducing electric currents in the mandrel (col. 3, lines 51-62) thereby dissolving/melting the mandrel. The examiner notes that melting is one of the definitions of the term dissolve. Further, the examiner notes that other dissolving mandrels, such as mandrels that are dissolved in solvents are also known and conventional in the art.

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Taylor and to have applied electric energy (e.g. electric currents in the mandrel) to the mandrel as suggested by Honningstad et al. for the purpose of removing the mandrel having desired properties in a convenient manner (col. 1, lines 10-53).

Claims 70 and 71 are rejected under 35 U.S.C. 103(a) as being obvious over Sutton (US 5,472,435) in view of any one of Keith et al. (US 5,888,436) or Chiu et al. (US 6,540,734) or Kolobow (US 5,429,127) or Crowley (US 5,840,031) and in view of either Brown et al. (US 5,558,737) or Stevens (US 3,585,707), as applied to claims 62-65, 67 and 69 above, and further in view of Honningstad et al. (US 3,113,897).

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examiner notes that melting is one of the definitions of the term dissolve. Further, the examiner notes that other "dissolving" mandrels, such as mandrels that are dissolved in solvents are also known and conventional in the art.

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Taylor and to have applied electric energy (e.g. electric currents in the mandrel) to the mandrel as suggested by Honningstad et al. for the purpose of removing the mandrel having desired properties in a convenient manner (col. 1, lines 10-53).

Response to Arguments

Applicant's arguments filed March 22, 2010 have been fully considered. Applicant's argument that Keith does not teach modifying the size or width of the mandrel is not persuasive. Keith teaches that upon completion of the microtubing, as the final step, cutting the mandrel (29 or 30) (i.e. modifying the mandrel's size) or cutting short segment "b" from the mandrel (i.e. modifying the mandrel size and also reducing the overall diameter/width of the mandrel) (col. 5, lines 8-25).

Further, applicant's arguments that none of the references recite a multiple part mandrel have been considered, but they are not persuasive. The examiner disagrees that the term "multiple part" is limited to separate pieces that have been put together to form a mandrel wherein these separate pieces can be later individually modified. The examiner maintains that a mandrel having different sections (e.g. stepped mandrel with a thicker part and a thinner part or a mandrel having a repeating pattern such as Keith (Figure 1C)) is very reasonably understood to have "multiple parts" when interpreted in view of the instant specification (i.e. the specification does not clearly teach or suggest the term is to be defined only as argued and

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there is nothing to suggest such an interpretation is not reasonable). Further, the examiner notes that should such a narrow interpretation of the term be applied or required, such mandrels are known in the molding arts and would be readily employed as required absent a clear showing of unexpected results (e.g. US 3,354,695; US 5,945,048; US 6,533,984).

Applicant's other arguments have been considered, but are moot in view of the new grounds of rejection necessitated by the amendment to the claims.

It is the examiner's positions that the claims would need to be further amended to overcome the art of record.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY WOLLSCHLAGER whose telephone number is (571)272-8937. The examiner can normally be reached on Monday - Thursday 6:45 - 4:15, alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeff Wollschlager/
Primary Examiner
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June 12, 2010